Congress of the United States
Washington, DC 20515

January 8, 2015

Dr. Robin Robinson
Director
Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Robinson:

Thank you for appearing before the Subcommittee on Health on Wednesday, November 19, 2014, to testify at the hearing entitled "Examining Medical Product Development in the Wake of the Ebola Epidemic."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, January 22, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Adrianna.Simonelli@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Attachment—Additional Questions for the Record

The Honorable Joseph R. Pitts

1. I believe having an effective Ebola vaccine would be a game changer in turning the tide of this outbreak and providing confidence to public health and medical providers on the front lines.

    a. Understanding that many early stage vaccine and drug candidates fail, how many vaccine candidates will BARDA be able to support with the $157 million requested?

    b. How far along the development pathway will that level of funding be able to get those candidate vaccines?

    c. Will that level of funding allow for large scale manufacturing scale-up?

    d. Does HHS intend to purchase an Ebola vaccine(s)?

2. Can you provide assurance to this Committee that the $157 million request for BARDA will be sufficient to prevent the agency from shifting funds away from the development of medical countermeasures for other priority biological threats identified by DHS?

3. Beyond the $157 million currently requested for BARDA, would the administration's proposed Ebola "Contingency Fund" be used for advanced research, development, and procurement of promising Ebola vaccines and therapeutics?

4. In testimony before the Senate Appropriations Committee last week, Dr. Fauci said the Administration's $157 million emergency funding request for BARDA would support the development of 2 Ebola vaccines. He also said BARDA has its eye on 3 more candidates, for a total of 5. What vaccine candidates are you looking at that do not yet have funding to support development?

5. What funding would you need to support the development of additional Ebola vaccines?

6. Does the emergency funding request for BARDA allow for the scale-up and manufacturing of these vaccines should one or more of them are successful?

7. HHS has now funded the development of several Ebola vaccine candidates in response to the outbreak in West Africa. We all hope one or more of these products will be successful in the near future. However, I believe HHS should already be planning ahead to ensure a successful vaccine can be successfully manufactured and stockpiled as soon as it is ready. Has BARDA committed to purchasing and stockpiling Ebola vaccines when they are ready? Does HHS have a long-term commitment to the successful development of Ebola vaccines?

8. The HHS response to Ebola clearly needs to be an "all hands on deck" effort. But I am concerned that as BARDA ramps up testing of Ebola treatments and vaccines, the development of countermeasures against all the other biological threats we face will be in jeopardy.

    a. How has the Ebola outbreak impacted BARDA's advanced research and development budget priorities?
    b. Have you had to shift funding to Ebola projects from other previously planned programs?
    c. Have development projects against other threats been shut down or postponed as a result?
    d. If so, how costly will it be to start them up again?

9. Although the Department of Homeland Security identified Ebola as a material threat to the U.S. 8 years ago, the level of financial priority and urgency placed on getting these Ebola countermeasures developed and stockpiled was insufficient to prepare us for the situation we currently face. What steps are you taking right now to ensure we are not caught flat-footed with the development of medical countermeasures for the next outbreak – whether it be a different Ebola strain or another threat like smallpox or tularemia?

10. The 2013 bipartisan reauthorization of federal biodefense programs [The Pandemic and All-Hazards Preparedness Reauthorization Act, Public Law 113-5] included numerous provisions designed to improve the development of medical countermeasures, like an Ebola vaccine. Specifically, HHS was tasked with producing a comprehensive 5-year budget plan to inform Congress about how you are prioritizing resources for the various countermeasures. Unfortunately, this plan was never submitted to Congress, even after asking you several times to submit this plan – most recently in the 2014 Omnibus. Why has the report release been delayed?

11. As you know, authority over all BARDA contracts is controlled by the Office of Acquisitions Management, Contracts and Grants (AMCG) in the Office of the Assistant Secretary for Preparedness & Response (ASPR). We have heard from MCM developers that this cumbersome arrangement has created confusion, unnecessary delays, and uncertainty regarding the time sensitive review of BARDA's MCM development contracts. Would it be more efficient and effective if BARDA was allowed to negotiate, manage, and award its own advanced R&D contracts, as it has done in the past? Would this policy change speed the development of critical MCM projects?

12. When Project BioShield was created in 2004, its funding was derived from DHS while the program was administered by HHS. At the time, it was necessary for all BioShield procurement contracts to be reviewed independently by OMB. However, now all BioShield funds are housed at HHS but the contracts are still required to be reviewed by OMB. This extra layer of bureaucracy has created unnecessary delays in critical MCM procurement contracts and made it harder for manufacturers to partner with the USG on countermeasure development. Would you support removing this additional layer of bureaucracy from the MCM review process?

13. Ten years ago, Congress recognized that many medical countermeasures needed to protect the American people do not yet exist and their development is a risky, expensive, and lengthy process. Because there is no commercial market for these products, we created Project BioShield to incentivize the private sector to develop these products. Without the promise of a government commitment to purchase these products, developers will likely abandon much of their work on developing these products. A decade later, BioShield has successfully procured and stockpiled millions of doses of vaccines and drugs to protect against many of the threats we face. Do you believe that the nation is capable of acquiring the medical countermeasures it needs to protect the U.S. people against threats like Ebola, Marburg, or smallpox in the absence of a BioShield Special Reserve Fund funded at anything less than the reauthorized levels?

14. Will the HHS budget request for FY2016 include funds at the levels authorized and required to adequately fund BARDA and the SRF to develop the needed countermeasures for our national stockpile?

15. In 2006, the Department of Homeland Security determined hemorrhagic viruses, like Ebola, are material threats to the U.S. as potential bioweapons. In this case, the widespread availability of Ebola might present an increased security risk of a terrorist acquiring the virus for deliberate use. How does this Ebola risk compare to other identified threats, such as smallpox and anthrax?

16. What initiatives are underway at the Department of Health and Human Services (HHS) to improve care for patients who are infected with Ebola today?

17. Given many of the well-reported supply challenges with mass-producing and manufacturing Ebola drug treatments, such as ZMapp and others, in the near-term pipeline of Ebola experimental and investigational treatments, are there potential options that could have the drug supply available to actually treat thousands of Ebola patients in West Africa?

18. What is the role and pathway to join the global coalition of clinical trials for finding effective new experimental therapies in patients with Ebola Virus Disease in West Africa?

19. How would a treatment that focused on surviving the deadly complications of Ebola rather than the virus itself be tested in the coalition forming for clinical trials in West Africa?

20. For experimental treatments that are available today, what funds are being made available to rapidly test them to improve outcomes in patients in West Africa for patients with Ebola?

The Honorable Dr. Michael C. Burgess

1. It is reported that the physician who is now deceased, who was transported from Sierra Leone to the University of Nebraska Medical Center, and passed away on Monday received ZMapp upon his transfer.
    a. Do we now have a new supply of ZMapp?
    b. If so, how big is it?
    c. Where did this come from? Is this a part of the unfunded task order BARDA released recently for bids?

2. It is my understanding that task orders have been put on hold, one being the production of an anthrax vaccine. What else are you delaying at BARDA?